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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,829	11/15/1999	ALEX CHENCHIK	CLON-015	3481
24353	7590	03/30/2004		
BOZICEVIC, FIELD & FRANCIS LLP			EXAMINER	
200 MIDDLEFIELD RD			FORMAN, BETTY J	
SUITE 200			ART UNIT	
MENLO PARK, CA 94025			PAPER NUMBER	
			1634	

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/440,829	CHENCHIK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 20 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-3,7-23 and 35 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,10-23 and 35 is/are rejected.
- 7) Claim(s) 7-9 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 January 2004 has been entered.

***Status of the Claims***

2. This action is in response to papers filed 20 January 2004 in which claims 1, 14 and 23 were amended and a declaration under 37 C.F.R. § 1.131 was submitted. The amendments have been thoroughly reviewed and entered.

The previous rejections over Linsley et al are withdrawn in view of the declaration filed 20 January 2004. The previous rejections over Ebersole et al are withdrawn in view of the amendments and declaration filed 17 March 2003. The previous rejections over Chrisey et al are withdrawn in view of the declaration filed 17 March 2003 wherein unexpected results were asserted; state of the art was discussed including the lack of motivation for using the instantly claimed range; and post-filing date publications by other laboratories using the claimed range.

New grounds for rejection are discussed.

Claims 1-3, 7-23 and 35 are under prosecution.

***Specification***

3. The disclosure is objected to because of the following informalities: Pages 18 and 19 include references to numerous co-ending applications. The references are not updated to reflect current status and application and/or patent number.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-3, 7-23 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Claims 1-3, 7-13 and 35 are indefinite in Claim 1; Claims 14-22 are indefinite in Claim 14; and Claim 23 is indefinite for the recitation "at least about". It is vague and indefinite what is meant by the phrase "at least about 10/cm<sup>2</sup>". The phrase "at least" typically indicates a minimum point. The phrase "at least" however, is contraverted by the term "about" which implies that values above and below 10/cm<sup>2</sup> are permitted. Further, the extent of variance permitted by "about" is unclear in this context because it is also unclear if "about 10/cm<sup>2</sup>" simply includes 9 and 11/cm<sup>2</sup> or if it also includes 7-14/cm<sup>2</sup> as well. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the

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district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification.

b. Claims 8 and 9 are each indefinite for the recitation "site" because it is unclear whether the claimed "site" refers to one of the oligonucleotide "spots" of Claim 1 or whether the claimed "site" refers to some undescribed element of the array.

c. Claims 10, 11, 19 and 20 are each indefinite for the recitation "the number of spots on said array do not exceed a density of about 1000/cm<sup>2</sup> (400/cm<sup>2</sup>) because the recitation "do not exceed" typically indicates a maximum point. However, the recitation is contraverted by the term "about" which implies values above and below 1000/cm<sup>2</sup> (400/cm<sup>2</sup>).

Further, the extent of variance permitted by "about" is unclear in this context because it is also unclear if "about 1000/cm<sup>2</sup>" simply includes 900 and 1100/cm<sup>2</sup> or if it also includes 700-1400/cm<sup>2</sup> as well. As such, the claims are indefinite because the metes and bounds of the term are not defined.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 1-3 and 10-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Barany et al (U.S. Patent No. 6,506,594, filed 16 March 2000 and claiming priority to 60/125,357, filed 19 March 1999).

The claims are broadly drawn to "probe oligonucleotide spots stably attached to the surface of a solid support". The claims do not require probes directly and/or covalently attached to the support, but instead required "spots stably attached". The specification defines "stably associated" on page 13, as follows:

By "stably associated" it is meant that the oligonucleotides of the spots maintain their position relative to the solid support under hybridization and washing conditions. As such, the oligonucleotide members which make up the spots can be non-covalently or covalently stably associated with the support surface based on technologies well known to those of skill in the art. Examples of non-covalent association include non-specific adsorption, binding based on electrostatic (e.g. ion, ion pair interactions), hydrophobic interactions, **hydrogen bonding interactions**, specific binding through a specific binding pair member covalently attached to the support surface, and the like.

The claims are given the broadest reasonable interpretation consistent with the broad claim language and specification wherein stably associated encompasses almost any means of attaching probes and/or spots to the surface of the solid support including hybridization i.e. hydrogen bonding.

Regarding Claim 1, Barany et al disclose an array comprising at least one pattern of probe spots stably attached to the surface of a glass support wherein the spots on the array have a density of at least 10/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15) and each probe spot comprises probes that range in length from 60 to about 100 nucleotides e.g. 70bp (Examples 17 and 24 Column 73, line 61-Column 74, line 6).

Regarding Claim 2, Barany et al disclose their array wherein two or more different targets hybridize to different probe spots in the pattern (Example 15-17).

Regarding Claim 3, Barany et al disclose their array wherein each spot hybridizes to a different target (Examples 15-17).

Regarding Claim 10, Barany et al disclose the array wherein the spots do not exceed a density of about 1000/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 11, Barany et al disclose the array wherein the spots do not exceed a density of about 400/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15 0).

Regarding Claim 12, Barany et al disclose the array wherein the spots range from about 50 to 50000 in number (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 13, Barany et al disclose the array wherein the spots range from about 50 to 10000 in number (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 14, Barany et al disclose an array comprising at least one pattern of probe spots covalently attached to the surface of a glass support wherein the spots on the array have a density of at least 10/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15) and each probe spot comprises long probe composition (i.e. the composition comprises probes and capture probes) wherein the probes range in length from 60 to about 100 nucleotides e.g. 70bp (Examples 17 and 24 Column 73, line 61-Column 74, line 6).

Regarding Claim 15, Barany et al disclose the array wherein said array comprises ten or more different probe spots (Column 34, lines 27-58 and Fig. 14-15) each spot hybridizes to a different target (Examples 15-17).

Regarding Claim 16, Barany et al disclose their array wherein two or more different targets hybridize to different probe spots in the pattern (Examples 15-17).

Regarding Claim 17, Barany et al disclose their array wherein each spot hybridizes to a different target (Examples 15-17).

Regarding Claim 18, Barany et al disclose the array wherein the probes range in length from about 65 to 90 e.g. 70bp (Examples 17 and 24 Column 73, line 61-Column 74, line 6).

Regarding Claim 19, Barany et al disclose the array wherein the spots do not exceed a

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density of about 1000/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 20, Barany et al disclose the array wherein the spots do not exceed a density of about 400/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 21, Barany et al disclose the array wherein the spots range from about 50 to 50000 in number (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 22, Barany et al disclose the array wherein the spots range from about 50 to 10000 in number (Column 34, lines 27-58 and Fig. 14-15).

Regarding Claim 23, Barany et al disclose an array comprising at least one pattern of probe spots covalently attached to the surface of a glass support wherein the spots on the array have a density of at least 10/cm<sup>2</sup> that does not exceed 400 cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15) and each probe spot comprises long probe composition (i.e. the composition comprises probes and capture probes) wherein the probes range in length from 65 to about 90 nucleotides e.g. 70bp (Examples 17 and 24 Column 73, line 61-Column 74, line 6).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barany et al (U.S. Patent No. 6,506,594, filed 16 March) in view of Stratagene catalog (1989, page 29).

Regarding Claim 35, Barany et al disclose an array comprising at least one pattern of probe spots stably attached to the surface of a glass support wherein the spots on the array have a density of at least 10/cm<sup>2</sup> (Column 34, lines 27-58 and Fig. 14-15) and each probe spot comprises probes that range in length from 60 to about 100 nucleotides e.g. 70bp (Examples 17 and 24 Column 73, line 61-Column 74, line 6).

Barany et al do not teach their array in a kit format. Stratagene catalog teaches a motivation to combine reagents into kit format (page 39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the array of Barany et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

#### ***Allowable Subject Matter***

10. Claims 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**Conclusion**

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
BJ Forman, Ph.D.  
Primary Examiner  
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March 26, 2004